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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,011	02/14/2001	Contreras	JAB-1415	1386

7590 06/16/2005

EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

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DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,011	CONTRERAS,	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,22-26,28-35 and 38-48* is/are pending in the application.

4a) Of the above claim(s) *3,5,10-14,22-26, 28-34 and 38-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-9,15-17 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Mar 2002; Oct 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a response, filed 4/11/2005, amending claims 1-2, 4, and 10. Claims 1-48 are pending in this application. Claims 1-4, 6-9, 15-17 and 35 are under consideration in this action.

Election/Restrictions

Applicant's election with traverse of Group I and SEQ ID NO: 1 (claims 1-4, 6-8, 15-17, 35 and 40) in the reply filed on 04/11/2005 is acknowledged. The traversal is on the ground(s) that there would be no undue search burden to examine the nucleic acid of SEQ ID NO: 1 and the corresponding polypeptide of SEQ ID NO: 10. (Remarks, p. 9). Furthermore, Applicant asserts that claims 9 and 10 should also be examined, as there would not be an undue burden to do so.

Claim 9 is rejoined as the claim is directed to a shared special technical feature, vis-à-vis claim 1 and SEQ ID NO: 1. Claim 10 is not rejoined because an *antisense* molecule inheres a distinct special technical feature that extends beyond mere hybridization (i.e., antisense molecules function to hinder/preclude transcription or translation). Therefore, claims 9 and 10 are distinguishable, because where a molecule hybridizes under stringent conditions, the act of *hybridizing* is the function that corresponds to the nucleic acid molecule of claim 9.

Further, with respect to Applicant's additional assertions, they are not found persuasive. First, Applicant appears to concede that the inventions (nucleic acid of SEQ ID NO: 1 versus polypeptide of SEQ ID NO: 10) are directed to distinct special technical features (i.e., nucleic acid encoding a protein versus protein which inheres a particular function/structure).

Second, although undue search burden is not technically a ground for restriction under the applicable rules (i.e., PCT rules 13.1 and 13.2; 37 CFR 1.499), a search for a nucleic acid sequence would not necessarily be coextensive with that for a protein. For example, a gene may have been analyzed in the prior art without regard to any open reading frame comprised therein. In any event, the salient point is that restriction is proper where inventions are directed to distinct special technical features, as is the case here. Therefore, the requirement is still deemed proper and is therefore made FINAL.

With respect to claim 40, as written the claim is directed to nonelected subject matter, thus withdrawn from consideration (i.e., drawn to sequences other than elected SEQ ID NO: 1).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

> It was not executed in accordance with either 37 CFR 1.66 or 1.68. More particularly, it appears inventors Nelissen and Luyten have not signed the oath.

Specification

The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

On page 18, line 10, a period appears to be missing, so as to form a complete sentence. On page 37, ll. 15-18, the phrase "not always both copies of a gene are functional" is grammatically incorrect (e.g., replace with "both copies of a gene are not always functional"). On page 37, line 18, there appears a typographical error (i.e., "correct" in place of "corerct"). On page 38, l. 15, the sentence beginning with the phrase, "The second copy of the gene has no more a promoter...", ending on line 20, is grammatically incorrect and incomprehensible, as it appears parts have been omitted (i.e., line 19). Appropriate correction is required.

In addition, on page 30, a reference is made to a publication (i.e., Hinnebusch and Liebman, 1991), but no such publication appears in the nonpatent literature. If Applicant is aware of such a publication, it is requested that a copy of said reference be submitted in any response to this action. If the reference is in error, then correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. **Claims 1-2, 4 and 6-9 rejected under 35 U.S.C. 101**

The recited nucleic acids can be naturally occurring (i.e., products of nature). In addition, there are naturally occurring vectors (e.g., viruses) that can contain said sequences. As such the claimed invention is directed to non-statutory subject matter. It would be remedial to insert the term "isolated" before the term "nucleic acid".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. **Claims 1-2, 4 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The recited "nucleic acid molecule" can be in an in vitro environment. If it is in an in vivo environment, it is unclear what applicants are claiming because the nucleic acid would be a part of a cell, i.e. are applicants claiming a naturally occurring cell. It would be remedial to include "isolated" before the term "nucleic acid" to clarify the metes and bounds of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 1-2 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.**

The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More particularly, the claims are directed to a genus of nucleic acid molecules, wherein said genus is comprised of a subgenus of nucleic acid molecules having at least 70% homology to SEQ ID NO: 1, or a subgenus of nucleic acid molecules that are a "fragment or derivative" of SEQ ID NO: 1.

Said nucleic acid molecules (i.e., structures) must correlate to a function of encoding a polypeptide that is "critical for survival and growth of the yeast Candida albicans". Given the size of SEQ ID NO: 1, the genus comprises tens of thousands of potential nucleic acid molecules.

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings or by disclosure relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines Inc.* (CAFC) 41 USPQ2d 1961 (at 1966). Further, the Guidelines for Written Description state:

> "The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art" (Federal Register/ Vol. 66, No. 4/Friday, January 5, 2001/Notices, column 1, page 1105). "[t]he claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement" (at page 1105, center column, third full paragraph).

The critical feature in the instant claims is the nucleic acid structure as claimed and having the prescribed function of encoding a critical protein. Therefore, in the context of the instant claims, a sufficient description would identify a representative number of nucleic acid molecules that are at least 70% homologous to SEQ ID NO: 1, or that are fragments or derivatives of SEQ ID NO: 1, and correlate to function of encoding a protein that is itself critical

for *C. albican* survival and growth. The specification does not identify a representative number of embodiments comprised in the genus/subgenus of claimed nucleic acid molecules.

The specification discloses that SEQ ID NO: 1 encodes the protein SAM2 (e.g., Specification, p. 35), but there is no further clarification of particular domains, motifs, sequences, or any other structural feature, that can be identified as a necessary sequence that encodes a necessary portion of a protein that is critical for both survival and growth. No regions are disclosed that are at least 70% homologous to SEQ ID NO: 1 or that are fragments or derivatives thereof and that maintain the function of encoding a critical polypeptide or domains thereof. As a result, there is a gap in the disclosure with respect to identities of species that comprise the genus/subgenus of nucleic acid molecules that are claimed. Furthermore, this gap is not filled by knowledge available in the art. In other words, the art does not provide clarification of sequences that are 70% homologous to SEQ ID NO: 1, that are fragments or derivative of SEQ ID NO: 1 and that encode a critical protein or at least a critical portion of the protein that are necessary for *C. albican* growth and survival.

Given the enormous breadth of the nucleic acid molecules encompassed by the rejected claims, and given the limited description from the instant specification of such nucleic acid molecules, the skilled artisan would not have been able to envision a sufficient number of specific embodiments to describe the broadly claimed genus/subgenus. Moreover, an applicant claiming a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from other species. Therefore, the skilled artisan would reasonably have concluded that applicants were not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 1-2, 6-9, 15-17 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinstock et al. (US 6,747,137; see entire document; hereinafter '137 patent).**

The claims are directed to nucleic acid molecules that most particularly comprise a fragment having at least 70% homology to SEQ ID NO: 1 or having from 10 to 50 contiguous nucleic acid sequences of SEQ ID NO: 1. In addition, claims are directed to expression vectors comprising nucleic acid molecules comprising at sequences that are at least 70% homologous to SEQ ID NO: 1.

The '137 patent teaches the nucleic acid molecule of SEQ ID NO: 5972, which is 81% homologous to instant SEQ ID NO: 1. (e.g., col. 1272; col. 7, ll. 35-45; col. 8, ll. 5-20; col. 26). In addition, the nucleic acid molecules disclosed can be further comprised in expression vectors (e.g., col. 8, ll. 25-40), which include inducible promoters (e.g., col. 14, last ¶, bridging to col. 15; col. 20, ll. 1-65, bridging to col. 21; col. 25, ll. 25-55). In addition, the vectors can contain a reporter gene (i.e., selectable markers). (e.g., col. 20, last ¶). In sum, the '137 teaches all the limitations of the rejected claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 6-9, 15-17 and 35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 and 23-28 of copending Application No. 10/451,467.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims do not recite the same exact limitations, they are directed to indistinguishable subject matter.

The instant and reference claims are directed to nucleic acid molecules and expression vectors comprising said nucleic acid molecules, which are delimited to instant SEQ ID NO: 1 and reference SEQ ID NOs: 475, 579 and 687, each of which is at least 88.9% homologous to SEQ ID NO: 1. Therefore, the instant claims are obvious over the reference claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781.

The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636

Daniel M. Sullivan
Patent Examiner